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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,965	11/06/2000	Esmail Kiani-Azarbayjany	MLABS.018C3	8509

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EXAMINER

KREMER, MATTHEW J

ART UNIT PAPER NUMBER

3736

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/706,965

Applicant(s)

KIANI-AZARBAYJANY ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 12-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 12, 14, 16-19, 21, 23 and 24 is/are rejected.
- 7) ☒ Claim(s) 13, 15, 20 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/13/2004 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 12, 16-19, 23, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,372,135 to Mendelson et al. (Mendelson). Mendelson teaches a system for determining blood glucose. (column 1, lines 35-38 of Mendelson). The system includes a lamp 10 that emits a plurality of wavelengths, a pulse inducement device 26, a detector 32, and a signal processor 36. (Fig. 3 of Mendelson).

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The pulse inducement device 26 causes periodic changes in a volume of blood in the fleshy medium adjacent to the pulse inducement device (where Beam A goes through the tissue) with a level of inducement below a level that causes significant variations in the optical properties of the fleshy medium. (Fig. 4A and column 4, lines 31-44 of Mendelson). In regard to claim 12, the pulse inducement device 26 causes a periodic change in the volume of blood independent of the natural flow. (Fig. 4A and column 4, lines 31-44 of Mendelson). In regard to claims 17-19, Mendelson teaches a light source 10, a test site (Beam A's passage through the tissue), an active pulse inducement device 26, a detector 32, and a signal processor 36. (Fig. 3 of Mendelson). In regard to claim 23, Mendelson teaches an input 39 and a signal processor 36. (Fig. 3 of Mendelson). In regard to claim 24, Mendelson teaches a light source 10, a test site (Beam A's passage through the tissue), an active pulse inducement device 26, and a detector 32. (Fig. 3 of Mendelson).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,372,135 to Mendelson et al. (Mendelson) as applied to claims 1 and

17, and further in view of U.S. Patent 5,529,755 to Higashio et al. (Higashio).

Mendelson teaches the use of a clamp 26 (Fig. 3 of Mendelson) but does not teach the particulars of the clamp. Higashio teaches a clamp with an inflatable bladder (Fig. 1 and column 5, lines 34-42 of Higashio) that would fulfill the requirements of providing a clamp as set forth in Mendelson. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the clamp of Higashio in the device of Mendelson since Mendelson requires the use of a claim and Higashio teaches one such clamp.

Response to Arguments

6. Applicant's arguments with respect to claims 1, 12, 14, 17-19, 21, and 23-24 have been considered but are moot in view of the new ground(s) of rejection. This new ground of rejections is based on the Examiner's reconsideration of the Mendelson patent. The Examiner would like to address the Applicant's arguments that claims 1 and 12 are not anticipatory because Mendelson fails to teach or suggest causing a periodic change in a volume of blood in the fleshy medium with the level of inducement below a level that causes significant variations in the optical properties of the fleshy medium. The Applicant's contention is that Mendelson's teaches the movement of the fleshy medium in the test area, which affects the optical properties of the fleshy medium. The Examiner would like to note that Fig. 3 of Mendelson shows two testing sites: (1) Site A in which there is no movement of the fleshy medium (where Beam A transmits through the tissue) and (2) Site B in which there is movement of the fleshy

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medium (where Beam B transmits through the tissue). Both sites are used to determine glucose concentration. Site A is adjacent to the area where the tissue is moved (Site B) so there is no significant variations in the optical properties of Site A but there are periodic changes since the movement at Site B still effects Site A but to a lesser extent. This phenomenon is shown in Fig. 4A of Mendelson where the optical absorption of the two sites track each other in a periodic fashion. Because Site A's optical properties are not effected (even though its blood volume is) due to the actions of the inducement device 26, the limitations of the active pulse inducement device of the present application is anticipated by the Mendelson reference.

Allowable Subject Matter

7. Claims 13, 15, 20 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter. In regard to claim 13, neither Mendelson nor the prior art teaches or suggests that the active pulse inducement device causes a periodic change in the volume of blood in the fleshy medium in conjunction with the natural flow of blood in said fleshy medium that is combined or combinable with the other limitations of claim 13. In regard to claim 15, neither Mendelson nor the prior art teaches or suggests a receptacle comprising a temperature variation element in which the temperature variation element

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cyclicly varies the temperature of said fleshy medium in order to induce a change in the flow of blood in said fleshy medium that is combined or combinable with the other limitations of claim 15. In regard to claim 20, neither Mendelson nor the prior art teaches or suggests that the active pulse inducement device causes a periodic change in the volume of blood in the fleshy medium in conjunction with the natural flow of blood in said fleshy medium that is combined or combinable with the other limitations of claim 20. In regard to claim 22, neither Mendelson nor the prior art teaches or suggests a receptacle comprising a temperature variation element in which the temperature variation element cyclicly varies the temperature of said fleshy medium in order to induce a change in the flow of blood in said fleshy medium that is combined or combinable with the other limitations of claim 22.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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